

## **REMARKS/ARGUMENTS**

Applicant has carefully considered this Application in connection with the Examiner's Action, and respectfully request reconsideration of this Application in view of the above Amendment and the following remarks.

Claims 14-19 and 51 are currently pending. Claims 1-13, 20-50, 52, and 57-60 have been withdrawn. Claims 53-56 and 61 have been cancelled. Withdrawn Claim 1 has been amended to incorporate all of the limitations of product Claim 14. Withdrawn Claim 20 has been amended to incorporate all of the limitations of product Claim 40. Withdrawn Claim 52 has been amended to incorporate all of the limitations of product Claim 14.

Claims 17-19 have been amended to correctly depend from Claim 14, rather than non-elected Claim 13.

### **I. Election/Restrictions**

Although Applicant continues to respectfully disagree with the Examiner's assertions regarding the lack of unity of the claims, Applicant acknowledges that Claims 14-19 and 51 are currently pending in this application. Claims 1-13, 20-39, and 52-61 are withdrawn as being directed to a non-elected invention. Claims 40-50 are withdrawn as being directed to a non-elected species.

### **II. Claim Objections**

Claims 17-19 stand objected to because of their dependency from non-elected Claim 13. Applicant has amended Claims 17-19 to correctly depend from Claim 14 and respectfully requests that this objection be withdrawn.

### **III. Claim Rejections**

#### **A. 35 U.S.C. § 102(b)/103(a)**

Claims 14, 15, 17-19, and 51 stand rejected under 35 U.S.C. § 102(b) as anticipated by, or alternatively, under 35 U.S.C. § 103(a) as obvious in view of, U.S. Patent Publication No. 2002/0165616 in the name of Heide et al. ("Heide"). The Examiner asserts that Heide teaches a

bone substitute material having tubular pores and micropores that read on the claimed open cells. In addition, the Examiner asserts that Heide teaches a material that meets the structural and chemical limitations of the claims and would therefore inherently possess the same breaking stress. Applicant respectfully disagrees with the Examiner's arguments and asserts that Heide does not disclose or suggest the limitations of the claims.

In particular, independent Claims 14 and 51, as amended, require a bone substitute material having approximately the form of a positive image of an open celled foam material, **the walls defining the cells within the material being hollow**, which is a novel feature of the claimed subject matter, which results from a unique method of fabrication in one exemplary embodiment. As described in the specification at Page 1, ll. 17-18, the foam material used to fabricate the material itself has an open celled structure. Thus, the foam material has an open cavity running through its center. When the foam material is coated with the ceramic slip, this coating runs on the outside and inside of the open celled structure defined by the foam. Consequently, the specification emphasizes at Page 4, ll. 16-19 that air should be directed onto the coated foam material to inhibit the formation of closed cells. The walls of the foam material are better thought of as "struts," as the specification provides at Page 14, ll. 15-16. Once the foam material is heated and decomposed, the "struts" are missing, leaving the layer of ceramic that coated the outside and the inside of the open cells of the foam material. This exemplary process results in the claimed subject matter, which is not an improper attempt to import limitations from the specification into the claims but rather an exemplary process that can be used to result in the novel and non-obvious claimed subject matter.

Fabricating the claimed bone substitute material in this manner essentially results in a double wall defining the open cell. When two walls circumscribe the interior of the cell, a hollow wall is created. A hollow wall includes an empty space existing between layers of material that in turn define the center of the open cell. Heide provides no disclosure or teaching of such a method of fabrication. In its absence, Heide cannot suggest the existence of hollow walls.

By contrast, Heide merely describes pores, not hollow walled open cells. In reference to Heide, the Examiner states that "[t]here is no teaching or suggestion that the bone substitute material is filled with other material; therefore, the walls defining the tubular pores within the

material are hollow.” See Office Action, Page 4. Applicant respectfully asserts that this is not a proper characterization of hollow walls falling within the scope of the claims. Based on the plain meaning of the term, a hollow pore is not a hollow wall surrounding a hollow pore. Heide’s pores are circumscribed by the solid material through which they pass and nothing more. Thus, the “walls” of Heide’s pores are as solid as the rest of the surrounding material. Heide certainly does not utilize a double-walled structure in order to produce a hollow space within the walls.

More specifically, Heide discusses at Paragraph [0045] that the formation material “is in block form,” with the tubular pores “passing through each block.” It is the block that defines the walls of Heide’s pores, which means the walls cannot be hollow. Heide also notes at Paragraph [0050] that appropriate pore spacing determines the thickness of the walls of the pores and states that thickness should be “not more than 1500 to 4000  $\mu\text{m}$  and especially from 2000 to 3000  $\mu\text{m}$ .” This further explains that Heide’s pore walls are solid portions of the block formation material that exist between the pores. Heide does not disclose or suggest hollow walls.

Because Heide’s material does not have hollow walls and because Heide’s material is not prepared using the exemplary and unique method of fabrication that utilizes open celled foam material coated on the outside and inside, it is apparent that Heide’s material cannot be assumed to possess an identical physical structure or chemical composition when compared to the claimed material. Heide’s material is a block formation material with tubular pores passing through it. By contrast, the claimed material covers an open celled foam material, with the walls defining the cells within the material being hollow. Open cells do not equate to “pores” as that term is commonly understood. In view of these significant differences, the reasoning of *In re Spada*, 15 U.S.P.Q. 2d 1655 (Fed. Cir. 1990) is not applicable. Heide’s material cannot be assumed to possess the same properties as the claimed material. For that reason, it is inappropriate to assume that Heide’s material has a breaking stress of more than 1 MPa, or that Heide’s material possesses any other properties found in the claimed subject matter.

In view of these reasons, Applicant respectfully asserts that Heide does not disclose or suggest all limitations of independent Claims 14 and 51, and consequently does not disclose or suggest all limitations of dependent Claims 15 and 17-19. Claims 14, 15, 17-19, and 51 are patentable over Heide.

**B. 35 U.S.C. § 103(a)**

Claim 15 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Heide. The Examiner states that Heide does not disclose tubular pores having a length in one direction more than 20% greater than their length in the other perpendicular directions. However, the Examiner argues that diameter/length ratio is a result-effective variable that does not confer patentability in the absence of evidence of unexpected results. Applicant respectfully asserts that Heide does not teach or suggest all limitations of Claim 15.

Claim 15 depends from Claim 14, which includes a bone substitute material having approximately the form of a positive image of an open celled foam material, the walls defining the cells within the material being hollow. As already discussed above, Heide does not disclose or suggest a material with open cells having hollow walls. Heide's material consists of tubular pores passing through a solid block material. By contrast, the claimed material contains open cells defined by hollow walls. In one exemplary process, the coating of open cell foam material on the inside and outside, followed by the removal of the foam material, creates these double walled structures that contain an open space between the walls as well as in the center. Heide does not teach or suggest this type of fabrication nor this type of structure. For that reason, Heide does not teach or suggest the limitations of Claim 14 or its dependent Claim 15.

In view of these arguments, Applicant respectfully asserts that Claim 15 is patentable over Heide.

**C. 35 U.S.C. § 102(e)**

Claims 14-19 and 51 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Publication No. 2005/0049715 to Ito et al. ("Ito"). The Examiner asserts that Ito discloses a bone substitute material comprising tubular pores reading on the claimed open cells. Applicant respectfully disagrees and asserts that Ito also fails to disclose open cells having hollow walls.

As already noted, Claims 14 and 51 require a bone substitute material having approximately the form of a positive image of an open celled foam material, the walls defining the cells within the material being hollow. As was the case with Heide, Ito also fails to disclose hollow walls. Once again, the Examiner states that "[t]here is no teaching or suggestion that the

bone substitute material is filled with other material; therefore, the walls defining the tubular pores within the material are hollow.” See Office Action, Page 6. Applicant respectfully asserts that this statement again incorrectly equates hollow pores with hollow walls surrounding hollow pores. Ito may disclose hollow pores, but Ito does not disclose hollow pores that are circumscribed by hollow walls.

Ito’s disclosed method of fabrication does not permit the formation of the double walls that can create hollow walls surrounding an open cell. Paragraph [0009] of Ito describes the use of long columnar bodies disposed within the formation material to create the open pores. Paragraph [0030] of Ito describes how these long columnar bodies, depending on their composition, are removed from the compression molded product or how they will disappear during firing. It is apparent from this disclosure in Ito that Ito’s material contains merely hollow pores passing through a solid material. Again, as described above, this is not a disclosure of hollow walls defining an open cell. For that reason, Ito does not anticipate independent Claims 14 or 51, nor dependent Claims 15-19.

Applicant respectfully asserts that Claims 14-19 and 51 are patentable over Ito.

**D. 35 U.S.C. § 102(b)**

**1. U.S. Patent Publication No. 2002/0022885 to Ochi**

Claim 51 stands rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent Publication No. 2002/0022885 to Ochi (“Ochi”). The Examiner asserts that Ochi discloses a porous sintered ceramic body having a network of open pores interconnected to each other. Applicant respectfully asserts that in view of the amendment to Claim 51, Ochi does not anticipate this claim. Ochi does not disclose hollow walls.

Claim 51 has been amended to include that the walls defining the open cells within the material are hollow. As the Examiner has noted, Ochi discloses in the Abstract a series of globular pores located within a sintered body of calcium phosphates. These globular pores have walls that are made up of solid portions of the body of calcium phosphates located between the pores. As described in Paragraphs [0027]-[0028], Ochi’s pores are created through the stabilization of cross-polymerizable resin followed by grain growth of raw materials in the areas

between the pores. These raw materials create the pore walls, which have “a dense microstructure.” See Ochi, Paragraph [0027]. This disclosure of Ochi plainly reveals that Ochi does not disclose hollow walls defining the pores. Again, Ochi may disclose hollow pores, but Ochi does not disclose hollow walls surrounding the hollow pores. For this reason, Ochi does not disclose all limitations of Claim 51, as amended.

Applicant respectfully asserts that Claim 51 is patentable over Ochi.

## **2. U.S. Patent No. 6,340,648 to Imura et al.**

Claim 51 stands rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,340,648 to Imura et al. (“Imura”). The Examiner asserts that Imura discloses a porous sintered ceramic body having a network of open pores interconnected to each other. Applicant respectfully asserts that in view of the amendment to Claim 51, Imura does not anticipate this claim. Imura does not disclose hollow walls.

Claim 51 has been amended to include that the walls defining the open cells within the material are hollow. As the Examiner has noted, Imura discloses in the Abstract a series of spherical pores located within a sintered body of calcium phosphate. Imura describes producing the porous sintered body by using a slurry containing calcium phosphate powder that is made porous or dense depending on the sintering temperature. See Imura, Col. 6, ll. 20-31. Imura does not use a fabrication method similar to the exemplary disclosed process that can be used to create the claimed material, in which an open celled foam material is coated on the inside and outside to produce hollow walls defining open cells. Imura does not disclose hollow walls. For this reason, Imura does not disclose all limitations of Claim 51, as amended.

Applicant respectfully asserts that Claim 51 is patentable over Imura.

## **E. WO 03/026714**

Applicant thanks the Examiner for noting that WO 03/026714 does not teach or suggest a bone substitute material meeting the limitations of the pending claims.

**CONCLUSION**


In view of the foregoing remarks and for various other reasons readily apparent, Applicant submits that all of the claims now present are allowable, and withdrawal of the rejection and a Notice of Allowance are courteously solicited.

If any impediment to the allowance of the claims remains after consideration of this amendment, a telephone interview with the Examiner is hereby requested by the undersigned at (214) 953-5990 so that such issues may be resolved as expeditiously as possible.

The Commissioner is hereby authorized to charge any fee or credit any refund to Deposit Account No. 10-0096.

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Respectfully submitted,

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